IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY, GENEOHM SCIENCES CANADA, INC. and HANDYLAB, INC.,	)	
Plaintiffs,	)	C.A. No. 19-1126-LPS
v.	)	**DEMAND FOR JURY TRIAL**
NEUMODX MOLECULAR, INC.,	)	
Defendant.	)	

DEFENDANT NEUMODX MOLECULAR, INC'S FIRST AMENDED ANSWER TO PLAINTIFF'S COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant NeuMoDx Molecular, Inc. ("NeuMoDx") answers Plaintiffs Becton, Dickinson and Company, GeneOhm Sciences Canada, Inc. (collectively "BD"), and HandyLab, Inc. ("HandyLab" and collectively with BD, "Plaintiffs") Complaint for Patent Infringement (the "Complaint") as follows:

NATURE OF THE ACTION

1. No response is necessary for this statement.

2. NeuMoDx admits that Plaintiffs brought the present action, but denies that it has infringed any of Plaintiff's patent rights, including the Asserted Patents, or that Plaintiffs are entitled to any relief.

THE PARTIES

3. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 3, and therefore denies same leaving Plaintiffs to their proofs.

4. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 4, and therefore denies same leaving Plaintiffs to their proofs.

5. Admitted.

JURISDICTION AND VENUE

6. Paragraph 6 states a legal conclusion and therefore no response is required. NeuMoDx does not dispute subject matter jurisdiction.

7. Admitted in part and denied in part. NeuMoDx admits that this Court may exercise personal jurisdiction over NeuMoDx. However, NeuMoDx denies the remaining allegations in paragraph 7.

8. Admitted in part and denied in part. NeuMoDx admits that venue is proper in this District. However, NeuMoDx denies the remaining allegations in paragraph 8, including that Delaware is the most convenient forum for litigating this action.

FACTUAL ALLEGATIONS

Background

9. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 9, and therefore denies same leaving Plaintiffs to their proofs.

10. Admitted.

11. Exhibits 7 and 8 speak for themselves and therefore no response is required on allegations based upon those documents. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 11, and therefore denies same leaving Plaintiffs to their proofs.

12. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 12, and therefore denies same leaving Plaintiffs to their proofs.

13. NeuMoDx admits that Jeff Williams founded Molecular Systems Corp. in 2012, and that Molecular Systems Corp. changed its name to NeuMoDx. NeuMoDx admits that Sundaresh Brahmasandra served as Vice President of Research and Development Assay

Development at BD after the HandyLab acquisition, but that Brahmasandra joined NeuMoDx as President in 2012 only after requesting and obtaining express written permission from BD. NeuMoDx admits that Williams and Brahamsandra are named inventors on the '708 and '900 patents asserted in the Complaint, and are aware of the Asserted Patents. NeuMoDx denies the remaining allegations in paragraph 13.

14. Denied.

15. NeuMoDx admits that it commissioned a review of patents no later than 2017 before making, using, selling or offering to sell NeuMoDx's molecular diagnostic products, which information was provided to BD on a confidential basis solely for the purpose of BD's consideration of NeuMoDx when NeuMoDx was being offered for sale, and which public disclosure by BD violates that obligation of confidentiality. NeuMoDx denies the remaining allegations in paragraph 15.

16. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 16, and therefore denies same leaving Plaintiffs to their proofs.

17. Denied.

The Asserted Patents

18. NeuMoDx admits that U.S. Patent No. 8,273,308 (the "'308 Patent") entitled "Moving Microdroplets in a Microfluidic Device" issued on September 25, 2012. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 18, and therefore denies same leaving Plaintiffs to their proofs.

19. NeuMoDx admits that U.S. Patent No. 8,703,069 (the "'069 Patent"), entitled "Moving Microdroplets in a Microfluidic Device" issued on April 22, 2014. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 19,

and therefore denies same leaving Plaintiffs to their proofs.

20. NeuMoDx admits that U.S. Patent No. 7,998,708 (the "'708 Patent"), entitled "Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel" issued on August 16, 2011. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 20, and therefore denies same leaving Plaintiffs to their proofs.

21. NeuMoDx admits that U.S. Patent No. 8,323,900 (the "'900 Patent"), entitled "Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel" issued on December 4, 2012. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 21, and therefore denies same leaving Plaintiffs to their proofs.

22. NeuMoDx admits that U.S. Patent No. 8,415,103 (the "'103 Patent"), entitled "Microfluidic Cartridge" issued on April 9, 2013. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 22, and therefore denies same leaving Plaintiffs to their proofs.

23. NeuMoDx admits that U.S. Patent No. 8,709,787 (the "'787 Patent"), entitled "Microfluidic Cartridge and Method of Using Same" issued on April 29, 2014. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 22, and therefore denies same leaving Plaintiffs to their proofs.

24. NeuMoDx admits that as co-inventors of the '708 and '900 patents, Williams and Brahamsandra had knowledge of the '708 and '900 patents at some point after the' 708 patent issued on August 16, 2011 and the '900 patent issued on December 4, 2012. The citation of the Asserted Patents during the prosecution of NeuMoDx's patents, IPR2019-00488 and IPR2019-

00490 proceedings and Exhibit 9 speak for themselves and therefore no response is required on allegations based upon those documents. NeuMoDx admits that it commissioned a review of patents no later than 2017 before making, using, selling or offering to sell NeuMoDx's molecular diagnostic products, which information was provided to BD on a confidential basis solely for the purpose of BD's consideration of NeuMoDx when NeuMoDx was being offered for sale, and which public disclosure by BD violates that obligation of confidentiality. NeuMoDx denies the remaining allegations in paragraph 24.

NEUMODX'S INFRINGING PRODUCTS

25. Denied.

26. NeuMoDx admits that it manufactures and sells molecular diagnostic systems, including NeuMoDx™ 288 Molecular System (Product Code 500200) and NeuMoDx™ 96 Molecular System (Product Code 50100). NeuMoDx admits that it also manufactures and sells instruments, test strips and reagents, including NeuMoDx™ Cartridge (Product Code 100100); NeuMoDx™ GBS Test Strip (Product Code 200400); NeuMoDx™ LDT Master Mix, DNA (Product Code 210100); NeuMoDx™ LDT Master Mix, RNA (Product Code 310100); and NeuMoDx™ LDT Primer/Probe Strip (Product Code). NeuMoDx admits that its products are featured on its website. NeuMoDx denies the remaining allegations in paragraph 26.

27. NeuMoDx admits that its website links to videos showing operation of the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems. NeuMoDx admits that its website links to Vimeo hyperlinks https://vimeo.com/281470603 and https://vimeo.com/299307936. NeuMoDx denies the remaining allegations in paragraph 27.

28. Admitted.

COUNT 1
(INFRINGEMENT OF THE '308 PATENT)

29. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Complaint.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

34. Denied.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

COUNT 2
(INFRINGEMENT OF THE '069 PATENT)

39. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Complaint.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

COUNT 3
(INFRINGEMENT OF THE '708 PATENT)

47. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Complaint.

48. Denied.

49. Denied.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

COUNT 4
(INFRINGEMENT OF THE '900 PATENT)

56. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Complaint.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

65. Denied.

COUNT 5
(INFRINGEMENT OF THE '103 PATENT)

66. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Complaint.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

COUNT 6
(INFRINGEMENT OF THE '787 PATENT)

75. NeuMoDx incorporates and references its answers to the preceding paragraphs of the Complaint.

76. Denied.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

AFFIRMATIVE DEFENSES

First Affirmative Defense (Invalidity)

The '308, '069, '708, '900, '103, and '787 patents are invalid and/or unenforceable under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including for the failure to meet one or more of the requirements for patentability as specified in at least 35 U.S.C. §§ 101, 102, 103, and/or 112, as detailed below in NeuMoDx's counterclaims.

Second Affirmative Defense (Non-Infringement)

NeuMoDx has not infringed, contributed to the infringement of, or induced the infringement of any valid claim of the asserted '308, '069, '708, '900, '103, and '787 patents, either directly or indirectly, literally or under the doctrine of equivalents.

Third Affirmative Defense (Inequitable Conduct Relative to the '708 and '900 Patents)

The '708 and '900 patents are unenforceable due to inequitable conduct, as detailed below in NeuMoDx's counterclaims.

Fourth Affirmative Defense (Equitable Estoppel/Acquiescence/Waiver/Unclean Hands)

Plaintiffs are barred, in whole or in part, from recovering the relief sought in this action by the doctrine of equitable estoppel, acquiescence, waiver and/or unclean hands.

BD acquired HandyLab on November 19, 2009. Prior to the acquisition Jeff Williams was the CEO of HandyLab, and Sundaresh Brahmasandra was the Vice President of Product Development. Williams was not employed by BD after the acquisition but assisted with the transition for approximately one week at the request of BD and had a one year non-compete agreement with BD. Brahmasandra remained with BD as an employee until March 2011.

Brahmasandra's employment contract included a 2-year post-employment non-compete provision.

Williams continued his relationship with BD after the sale of HandyLab. In 2011, Williams, as CEO, facilitated the sale of Accuri Cytometers to BD. Also, in early 2011, and clear of his non-compete obligations, Williams contemplated a new company to pursue nucleic acid-based testing (molecular diagnostics) for higher throughput labs. Williams believed that an unmet need existed with a segment of customers in the molecular diagnostics market who desired a system that did not use unitized reagents and offered higher throughput, larger capacity, and more rapid turnaround time with better ease of use for medium to large hospital central laboratories and clinical reference labs. Williams formed Molecular Systems Corporation (MSC), the predecessor of NeuMoDx.

After completing his employment agreement with BD and BD's announcement that it would close the Ann Arbor facility, Brahmasandra left BD. Brahmasandra worked for another life-sciences company in Ann Arbor, and was subsequently invited to join MSC. However, Brahmasandra's non-compete agreement had not expired. Accordingly, in late 2011, Williams and Brahmasandra contacted senior executives at BD and shared Williams' intentions to actively pursue, with the support of venture capital, a startup nucleic acid testing systems company. Brahmasandra informed BD that he was interested in joining MSC, but that he was prevented from doing so because of the non-compete agreement with BD. Brahmasandra requested a waiver of his non-compete agreement to work with Williams at MSC to develop a nucleic acid-based system for performing rapid identification.

On December 21, 2011, BD, through a senior executive responsible for the diagnostics business, granted Brahmasandra's request based upon Williams and Brahmasandra's "good track

record." In return, BD asked for access to review MSC's technology for "future potential partnership interest." BD and Brahmasandra entered into an "Amendment to Employment Agreement" on February 23, 2012. BD acknowledged that "Employee (Brahmasandra) shall be permitted to engage in any activity relating to nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification contemplated by Molecular Systems Corporation", and that the "Proposed Business (MSC) shall not be deemed to Compete with or be Competitive with the Company (HandyLab) or any of its Affiliates for the purpose of this Agreement." The Amendment required Brahmasandra to use "commercially reasonable efforts" to schedule a meeting with "representatives of BD's exploratory technology group for the purpose of providing additional information about the Proposed Business, subject to the execution and delivery of a customary non-disclosure agreement… ."

Brahmasandra and MSC relied on BD representations, and Brahmasandra complied with his obligations. On several occasions during 2012 and 2013, NeuMoDx shared its business purposes, system architecture, technology, patents/patent applications and financing/financing plans with BD under confidentiality. In July 2013, NeuMoDx inquired with a senior BD executive about BD's interest in participating in a venture financing round of NeuMoDx. NeuMoDx provided a two-page summary of its system and technology and informed BD that NeuMoDX "had developed technology combining the best attributes of both integrated cartridge and microplate-based, liquid handling system, with the resulting platform to offer improved ease of use, lower costs, and higher performance compared to other nucleic acid testing systems."

After 2013, NeuMoDx met with representatives of BD at least annually at industry trade shows at which NeuMoDx provided BD with demonstrations of the NeuMoDx products and answered questions about the technology. The last such meeting was at a trade show in April of

2019. BD explained to NeuMoDx that the meetings were intended to keep BD informed about NeuMoDx's technology in the event BD was interested in "partnership interests" or acquiring NeuMoDx. During the parties' meetings, NeuMoDx shared its technology, including confidential aspects of its technology, with BD. At no point from 2012 to December 2018 did BD ever suggest that any NeuMoDx product violates or infringes any BD patents, let alone the patents acquired by BD from HandyLab. Furthermore, on several occasions BD R&D personnel and executives commented on the uniqueness and novelty of the NeuMoDx products.

On December 21, 2018, BD's VP of Strategy & Business Development for BD Life Sciences contacted Williams to express concern regarding IPR petitions filed by Qiagen against BD's '708 and '900 patents. Williams assured BD that NeuMoDx was not involved in Qiagen's IPR filings. Williams described the care taken by NeuMoDx to ensure that its products do not infringe third party patents, including those belonging to BD and HandyLab given the relationship between BD/HandyLab and NeuMoDx. Williams invited BD to Ann Arbor to see NeuMoDx's products. On February 4, 2019, Williams and Brahmasandra met with two executives from BD at NeuMoDx's facility in Ann Arbor. The parties focused their discussions on the IPRs, NeuMoDx's products and NeuMoDx's detailed explanation as why its products do not violate the '708 and '900 patents subject to the IPR petitions. The parties discussed trying to arrive at a reasonable resolution, but BD needed time to discuss internally.

In April of 2019, NeuMoDx spoke with BD again at a trade show, but BD had no updates from the parties' February 4, 2019 meeting. No further communication between NeuMoDx and BD occurred until after BD filed the complaint against NeuMoDx.

Upon information and belief, after portraying the parties' meetings as a way to foster potential collaborations between the parties', and encouraging NeuMoDx to share its confidential

product and technical information with BD to facilitate collaboration, BD is believed to have used NeuMoDx's confidential against it to file the present Complaint.

Fifth Affirmative Defense
(Breach of Contract)

On February 23, 2012, BD and Brahmasandra entered into an "Amendment to Employment Agreement." BD agreed that "Employee (Brahmasandra) shall be permitted to engage in any activity relating to nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification contemplated by Molecular Systems Corporation", and that the "Proposed Business (MSC) shall not be deemed to Compete with or be Competitive with the Company (HandyLab) or any of its Affiliates for the purpose of this Agreement." BD has now breached the Amended Agreement with Brahmasandra and MSC/NeuMoDx, the intended third party beneficiary of the Agreement, by suing NeuMoDx for the very nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification activity that BD agreed Brahmasandra and MSC/NeuMoDx could engage in, as detailed below in NeuMoDx's counterclaims.

Sixth Affirmative Defense
(Lack of Notice)

The patent owner of the '308, '069, '708, '900, '103, and '787 patents failed to provide notice pursuant to 35 U.S.C. §287 prior to filing the original complaint. Plaintiffs failed to provide constructive notice of the '308, '069, '708, '900, '103, and '787 patents by marking any products covered by the patents. Likewise, Plaintiffs failed to provide actual notice of the '308, '069, '708, '900, '103, and '787 patents prior to filing the Complaint on June 18, 2019. Therefore, Plaintiffs cannot recover damages for any alleged infringement that occurred prior to the filing of this case.

Seventh Affirmative Defense
(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim against NeuMoDx upon which relief can be granted.

COUNTERCLAIMS

PARTIES

1. Counterclaim Plaintiff NeuMoDx is corporation organized and existing under the laws of Delaware, with its principal place of business at 1250 Eisenhower Place, Ann Arbor, Michigan 48108-3281.

2. On information and belief, Counterclaim Defendant Becton, Dickinson and Company ("Becton Dickinson") is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 1 Becton Drive, Franklin Lakes, NJ 07417.

3. On information and belief, Counterclaim Defendant HandyLab is a wholly owned subsidiary of Becton Dickinson and a corporation organized and existing under the laws of Delaware, with at least some of the corporation's business activities located in Franklin Lakes, NJ.

4. On information and belief, GeneOhm Sciences Canada, Inc. is wholly owned subsidiary of Becton Dickinson and a corporation organized and existing under the laws of Canada, with its principal place of business 2555 Boul du Parc-Technologique Québec G1P4S5 Canada (Counterclaim Defendants collectively referred to as "BD").

JURISDICTION AND VENUE

5. This Court has subject matter of NeuMoDx's counterclaims under at least 28 U.S.C. §§ 1331, 1332, 1338(a), 1367, 2201 and 2202.

6. Counterclaim Defendants are subject to personal jurisdiction in this judicial district because they availed themselves of the jurisdiction of this Court, and engaged in acts giving rise to this controversy in this district.

7. Venue is proper under 28 U.S.C. §§ 1391 and pursuant to Fed. R. Civ. P. 13 because BD filed this action in this district.

GENERAL ALLEGATIONS

COUNT I – DECLARATORY JUDGMENT OF NON-INFRINGEMENT

8. NeuMoDx incorporates by reference paragraphs 1-7 of its counterclaims and its affirmative defenses above as though fully set forth herein.

9. BD has alleged that NeuMoDx is infringing U.S. Patent Nos. 8,273,308; 8,703,069; 7,998,708; 8,323,900; 8,415,103; and 8,709,787.

10. NeuMoDx's Accused Molecular Diagnostic Products do not infringe claims 1, 18 and 19 of the '308 patent (and any claims depending therefrom); claim 1 of the '069 (and any claims depending therefrom); claims 1 and 33 of the '708 patent (and any claims depending therefrom); claims 1, 7 and 20 of the '900 patent (and any claims depending therefrom); claims 1 and 15 of the '103 (and any claims depending therefrom); and claims 1, 9 and 10 of the '787 patent (and any claims depending therefrom), either directly or indirectly, because they does not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '308, '069, '708, '900, '103, and '787 patents.

11. NeuMoDx's Accused Molecular Diagnostic Products also do not infringe any do not infringe claims of the '308, '069, '708, '900, '103, and '787 patents, either directly or indirectly, because the '308, '069, '708, '900, '103, and '787 patents are invalid and thus cannot be infringed, for the reasons set forth in the following paragraphs, (¶¶14-24).

12. By reason of BD's charges of patent infringement, and NeuMoDx's denial of those charges, there exists a justiciable controversy between BD and NeuMoDx with respect to BD's assertion of infringement of the '308, '069, '708, '900, '103, and '787 patents and NeuMoDx's denial thereof.

13. NeuMoDx is entitled to a judgment under Rule 57 of the Federal Rules of Civil Procedure and 28 U.S.C. § 2201 declaring that NeuMoDx is not infringing and has not infringed the '308, '069, '708, '900, '103, and '787 patents and granting to NeuMoDx all other declaratory relief to which it may be entitled.

COUNT 2 – DECLARATORY JUDGMENT OF INVALIDITY

14. NeuMoDx incorporates by reference paragraphs 1-13 of its counterclaims and its affirmative defenses above as though fully set forth herein.

15. By implication of BD's allegations that NeuMoDx infringes one or more claims of the '308, '069, '708, '900, '103, and '787 patents, BD contends that the '308, '069, '708, '900, 103, and '787 patents are valid and enforceable.

16. NeuMoDx alleges that the claims of the '308, '069, '708, '900, '103, and '787 patents are invalid because they fail to comply with one or more requirements of the Patent Laws of the United States, 35 U.S.C. §1 et seq., including without limitation, §§ 101, 102, 103 or 112, as the claims of the patent are anticipated, obvious and/or indefinite, and that there is prior art and other evidence that anticipates or renders obvious the claims of the '308, '069, '708, '900, '103, and '787 patents.

17. Based upon NeuMoDx's ongoing investigation, the claims of the '708 patent are invalid in view of at least the prior art raised in IPR2019-00488 filed by Qiagen North American Holdings, Inc. against HandyLab, Inc, including but not limited to Zou I, U.S. Patent No.

6,509,186; McNeely, U.S. Patent App. Pub. No. US 2004/0037739; Pease, U.S. Patent App. Pub. No. US2004/0151629; Hsieh, U.S. Patent No. 7,122,799; Zou II, U.S. Patent No. 6,762,049; Duong, WO 01/54813; Chow, U.S. Patent No. 5,955,028; and Wilding U.S. Patent Publication No. 2003/0199081. The Patent Trial and Appeals Board ("PTAB") instituted trial on Claims 1-33 in a decision dated July 16, 2019, finding that "Petitioner has established a reasonable likelihood of prevailing with respect to claims 1-6, 9, 10, 18-20, 23-25, 28 and 33 of the '708 patent" and with respect to dependent claims 7, 8, 11-17, 21, 22, 26, 27 and 29.

18. Based upon NeuMoDx's ongoing investigation, the claims of the '900 patent are invalid in view of at least the prior art raised in IPR2019-00490 filed by Qiagen North American Holdings, Inc. against HandyLab, Inc, including but not limited to Zou I, U.S. Patent No. 6,509,186; McNeely, U.S. Patent App. Pub. No. US 2004/0037739; Pourahmadi, U.S. Patent App. Pub. US 2002/0055167; Zou II, U.S. Patent No. 6,762,049; Duong, WO 01/54813; Chow, U.S. Patent No. 5,955,028; and Wilding U.S. Patent Publication No. 2003/0199081. The Patent Trial and Appeals Board ("PTAB") instituted trial on Claims 1-22 in a decision dated July 16, 2019, finding that "Petitioner has demonstrated a reasonable likelihood that it will prevail on its challenge to at least one of the claims of the '900 patent."

19. Based upon NeuMoDx's ongoing investigation to date, the claims of the '308 patent are invalid pursuant to §§ 102 and/or 103 because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including: Neukermans, WO 97/22825; Mian, WO 97/21090; Lipshultz, U.S. Patent No. 5,856,74; Wilding, U.S. Patent No. 5,955,029; McNeely WO 00/22436; Nelson, U.S. Patent No. 6,007,690; Burns WO 99/01688; Wilding U.S. Patent Publication No. 2003/0199081; and Handique WO 00/17093.

20. Based upon NeuMoDx's ongoing investigation to date, the claims of the '069 patent are invalid pursuant to §§ 102 and/or 103 because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including: Neukermans, WO 97/22825 and Mian, WO 97/21090; Lipshultz, U.S. Patent No. 5,856,74; Wilding, U.S. Patent No. 5,955,029; McNeely WO 00/22436; Nelson, U.S. Patent No. 6,007,690; Burns WO 99/01688; Wilding U.S. Patent Publication No. 2003/0199081; and Handique WO 00/17093.

21. Based upon NeuMoDx's ongoing investigation to date, the claims of the '103 patent are invalid pursuant to §§ 102 and/or 103 because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including: Zou I, U.S. Patent No. 6,509,186; Mian, WO 97/21090; McNeely, U.S. Patent App. Pub. No. US 2004/0037739; Pease, U.S. Patent App. Pub. No. US2004/0151629; Hsieh, U.S. Patent No. 7,122,799; Zou II, U.S. Patent No. 6,762,049; Duong, WO 01/54813; Chow, U.S. Patent No. 5,955,028; Wilding U.S. Patent Publication No. 2003/0199081; and Pourahmadi, U.S. Patent App. Pub. US 2002/0055167.

22. Based upon NeuMoDx's ongoing investigation to date, the claims of the '787 patent are invalid pursuant to §§ 102 and/or 103 because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including: Zou I, U.S. Patent No. 6,509,186; Mian, WO 97/21090; McNeely, U.S. Patent App. Pub. No. US 2004/0037739; Pease, U.S. Patent App. Pub. No. US2004/0151629; Hsieh, U.S. Patent No. 7,122,799; Zou II, U.S. Patent No. 6,762,049; Duong, WO 01/54813; Chow, U.S. Patent No. 5,955,028; Wilding U.S. Patent Publication No. 2003/0199081; and Pourahmadi, U.S. Patent App. Pub. US 2002/0055167.

23. An actual and justiciable controversy exists between BD and NeuMoDx regarding the invalidity of the '308, '069, '708, '900, '103, and '787 patents.

24. NeuMoDx is entitled to a judgment under Rule 57 of the Federal Rules of Civil

Procedure and 28 U.S.C. § 2201 declaring that the claims of the '308, '069, '708, '900, '103, and '787 patents are invalid.

COUNT 3 - DECLARATION OF INEQUITABLE CONDUCT ('708 and '900 Patents)

25. NeuMoDx incorporates by reference paragraphs 1-24 of its counterclaims and its affirmative defenses above as though fully set forth herein.

26. The '708 patent was originally filed on November 14, 2007 and assigned to HandyLab, Inc.

27. Jeff Williams and Sundaresh Brahmasandra were identified as two of the four inventors of the '708 patent.

28. At the time of filing the '708 patent, Williams was the CEO of HandyLab, and Brahmasandra was the Vice President of Product Development of HandyLab.

29. When the '708 patent was filed, it was directed to an apparatus for carrying out PCR on a microdroplet of polynucleotide-containing sample in a microfluidic cartridge using a thermal heat source coupled to the cartridge, and detecting the presence of polynucleotides in the sample.

30. The original claims of the '708 patent included the following element: "at least one heat source thermally coupled to the cartridge and configured to carry out PCR on a **microdroplet** of polynucleotide-containing sample, in the cartridge."

31. The term "microdroplet" was expressly defined in HandyLab's prior '308 and '069 patents as a discrete sample having predetermined volume between about 1 picoliter and about 0.5 microliters. The '308, '069 and '708 patents all share at least one common inventor.

32. On July 13, 2009, HandyLab responded to an office action from the Examiner at the USPTO without amending the apparatus claims.

33. On November 19, 2009, BD acquired HandyLab.

34. On January 27, 2010, BD appointed the law firm of Knobbe, Martens, Olson & Bear, LLP ("Knobbe") as its attorneys to handle prosecution of the '708 patent, replacing the prior counsel that had been handling prosecution.

35. BD, acting through its new law firm Knobbe and Knobbe attorney Mr. Ned A. Israelson ("Mr. Israelsen") engaged in a pattern of misconduct involving false and misleading statements made to the United States Patent and Trademark Office ("USPTO") in order to obtain issuance of the '708 and '900 patents, thus violating their duty of candor and good faith and fair dealing required by USPTO's hallmark Rule 56.

36. On March 17, 2010, attorney Mr. Israelsen of the firm Knobbe, acting on behalf of and under the direction of BD, amended the claims of the '708 patent in a response to an office action from the Examiner at the USPTO. Mr. Israelsen, under the direction of BD, made substantial changes to independent claim 1, including both adding new claim language and striking language that originally appeared in the claim. Amongst the changes, Mr. Israelsen, acting on behalf of and under the direction of BD, removed the "microdroplet" limitation from the claims, broadening the claim to carrying out PCR on any polynucleotide **sample**, not just a microdroplet.

37. Neither Williams nor Brahmasandra were consulted regarding the change in claim scope, nor were they provided with an opportunity to review the change in the claim language to remove what they believed was an important aspect of their invention.

38. While Mr. Israelsen, acting on behalf of and under the direction of BD, made a number of arguments to the Examiner as to why BD's proposed claim amendments distinguish over the prior art cited by the Examiner, Mr. Israelsen did not mention, describe, identify, point

out or otherwise comment on the removal of the important "microdroplet" limitation to the Examiner at the USPTO.

39. Instead, Mr. Israelsen, acting on behalf of and under the direction of BD, told the Examiner: "Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language." Mr. Israelson's representation to the USPTO constitutes an affirmative, definitive statement asserting facts, not mere attorney argument.

40. Mr. Israelsen's statement to the USPTO, while he was acting on behalf of and under the direction of BD, was intentionally incorrect and affirmatively misleading, as the removal of the microdroplet limitation was not made to increase claim readability, improve grammar, or reduce the time and effort to understand the scope of the claim language. Rather, Mr. Israelsen's removal of the microdroplet limitation was an intentional and purposeful broadening of the claim beyond the scope of the invention contemplated by the inventors.

41. The statement quoted in ¶39 was not mere boilerplate language either. Upon information and belief, Mr. Israelsen's, false and misleading representations, while acting on behalf of and under the direction of BD, to the Patent Office were made with the intention of deceiving the USPTO, and diverting the Examiner's attention from broadening the claim without any substantive examination of the new, broadened aspect of the claims. This statement is not required by the USPTO's rules and regulations, and similar language was not used in other, later responses submitted by Mr. Israelson to the USPTO relative to the '708 patent, including

responses with claim amendments.

42. Mr. Israelsen's, false and misleading statements of fact, while acting on behalf of and under the direction of BD, were material to the examination of the claims of the '708 patent. The Examiner had already performed some prior art searching as part of the examination process with the claims requiring a microdroplet. Mr. Israelsen, removed the "microdroplet" limitation and broadened the claim while misrepresenting to the USPTO that the amendment was ministerial, and buried that change with a number of other claim amendments that were expressly identified and explained to the Examiner. On information and belief, and but for Mr. Israelsen's false representations, the Examiner would have conducted additional searching given the broader scope of the claim requiring only a sample, not a microdroplet, and would have appreciated the pertinence of references describing samples other than microdroplets. Instead, the Examiner's subsequent search queries focused on the new limitations that were added to the claims. (*See, e.g.*, '708 patent file history, May 26, 2010 Search Strategy and Results ("multiple with heat$4 with (mean source)"; "l3 and (microfluidic and PCR)"; "S2 and separately near4 heat$4").) On information and belief, if the Examiner had conducted a diligent search, the Examiner would have found a number of other prior art references that disclose the elements of the claims of the '708 patent, but not a microdroplet, including, for example, Zou I, U.S. Patent No. 6,509,186 and Zou II, U.S. Patent No. 6,762,049.

43. Because of Mr. Israelsen's intentionally false statements, while acting on behalf of and under the direction of BD, however, Mr. Israelsen hid the change in the claim scope from the Examiner, deceived the USPTO in order to lead the Examiner to focus on other claim amendments, and misled the Examiner into believing that no further searching or examination was required relative to the removal of the microdroplet limitation. Mr. Israelsen's

misrepresentations effectively prevented the USPTO from doing its job, which relies on patent applicants to comply with the duties of candor and good faith and fair dealing.

44. The Examiner issued another non-final rejection on May 26, 2010, which included rejecting the amended claims in view of Wilding, U.S. Patent Publication No. 2003/0199081. In a response dated August 17, 2010, Mr. Israelsen, acting on behalf of and under the direction of BD, amended the claims of the '708 patent and attempted to distinguish the amended claims from the cited Wilding prior art reference. Mr. Israelson and BD asserted that Wilding does not disclose either of the following limitations: (1) thermal cycling the PCR reaction zones; and (2) a multi-lane microfluidic cartridge, each lane comprising a PCR reaction zone.

45. Mr. Israelson, acting on behalf of and under the direction of BD, represented to the Examiner: "Wilding further fails to disclose 'thermal cycling the PCR reaction zones,' but instead maintains 22A and 22B at static temperatures and pumps the sample back and forth between them, i.e., between a relatively hot zone to a relatively cool zone."

46. Mr. Israelsen's statement to the USPTO, while he was acting on behalf of and under the direction of BD, was intentionally incorrect and affirmatively misleading. Wilding discloses a number of embodiments, including the first disclosed embodiments shown in Figures 1-3, that show a lane with single PCR reaction chamber with thermal cycling in the PCR reaction zone. A sample enters the single PCR reaction zone and endures thermal cycling between various temperatures while in that PCR reaction zone. Figures 1-3 are described in the specification, which specifically provides that the device may include means for thermally cycling the contents of the reaction chamber, including sequential heating and cooling of the sample in the reaction chamber. Wilding thus discloses the "thermal cycling the PCR reaction

zones" limitation.

47. Instead, Mr. Israelson intentionally misled the Examiner by directing the Examiner to the Fig. 4 embodiment of Wilding, which discloses a lane with two reaction zones where the sample is pumped back and forth between the reaction zones, in an attempt to distinguish Wilding from the amended claims, knowing that Fig. 4 is only one embodiment of Wilding and an embodiment that does not disclose thermal cycling in a single PCR reaction zone.

48. In the same August 17, 2010 response to the USPTO's office action, Mr. Israelson, acting on behalf of and under the direction of BD, represented to the Examiner: "The amplification device disclosed in Wilding is a single lane (flow channel) amplification device for conducting PCR. *See, e.g., Wilding*, paragraph [0039] and Figures 2 and 5. Thus, Wilding fails to disclose a 'multi-lane microfluidic cartridge, each lane comprising a PCR reaction zone' as required by Claim 1."

49. Mr. Israelson repeated this misrepresentation later in prosecution of the '708 patent, stating that, "Amended Claim 30 specifies 'introducing the plurality of samples into a multi-lane microfluidic cartridge, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples.' Wilding fails to disclose this limitation because, as described above, Wilding discloses a single lane (flow channel) amplification device."

50. Mr. Israelsen's statements to the USPTO, while he was acting on behalf of and under the direction of BD, are intentionally incorrect and affirmatively misleading. Wilding's specification provides that the microfluidic substrate may comprise a plurality of detection/reaction chambers to enable the rapid parallel detection of polynucleotides in a

mixture. Parallel detection of polynucleotides in a plurality of reaction chambers can only occur in a multilane system wherein each lane includes a reaction chamber that can process samples at the same time. Contrary to Mr. Israelson's false representations to the Examiner, Wilding thus discloses the "multi-lane microfluidic cartridge, each lane comprising a PCR reaction zone" limitation.

51. Mr. Israelson's intentionally false representations while he was acting on behalf of and under the direction of BD regarding Wilding during the '708 prosecution were material and made with the intent to deceive the USPTO, and in fact did deceive the Examiner into allowing the amended claims over Wilding.

52. Absent Mr. Israelson's false and misleading material representations to the USPTO, the Examiner would not have issued the claims of the '708 patent because Wilding discloses the claimed invention, including the claim elements misrepresented by Mr. Israelson as missing from Wilding's disclosure.

53. Mr. Israelson's pattern of misconduct, including Mr. Israelsen's false and misleading statements of fact, while acting on behalf of and under the direction of BD, violated Mr. Israelsen's and BD's duty of candor and good faith and fair dealing required by USPTO's Rule 56. The '708 patent is thus unenforceable due to inequitable conduct.

54. The '900 patent is likewise unenforceable due to the doctrine of infectious unenforceability or fruit of the poisonous tree, and due to the continued pattern of misconduct perpetrated by Mr. Israelson acting on behalf of and under the direction of BD in prosecuting the '900 patent.

55. The '900 patent was filed on February 25, 2011 and is a continuation of the '708 patent. The original claims of the '900 patent were similar to, and shared many of the same

elements of, the issued claims of the '708 patent. The original claims of the '900 patent also included limitations directed to a plurality of multilane cartridges and a plurality of receiving bays.

56. On November 1, 2011, the Examiner issued a non-final rejection of all the original claims of the '900 patent. The Examiner rejected the claims based upon a combination of prior art references, including the same Wilding, U.S. Patent Publication No. 2003/0199081, cited by the Examiner during prosecution of the '708 patent.

57. In a response dated January 31, 2012, Mr. Israelsen, acting on behalf of and under the direction of BD, made several of the same false and misleading statements of fact regarding Wilding to the USPTO. For instance, Mr. Israelson stated, "The amplification device disclosed in Wilding, however, is a single lane (flow channel) amplification device for conducting PCR . . . Wilding merely describes a device with a single PCR reaction zone and an appliance with one means for heating and/or cooling the single PCR reaction zone."

58. Mr. Israelsen, acting on behalf of and under the direction of BD, made similar false and misleading statements of fact to the USPTO in a May 10, 2012 response to non-final rejection: "Wilding merely describes a device with a single PCR reaction zone and an appliance with one means for heating and/or cooling the single PCR reaction zone."

59. Mr. Israelsen's statements to the USPTO while he was acting on behalf of and under the direction of BD were intentionally incorrect and affirmatively misleading. Wilding's specification provides that the microfluidic substrate may comprise a plurality of detection/reaction chambers to enable the rapid parallel detection of polynucleotides in a mixture. Parallel detection of polynucleotides in a plurality of reaction chambers can only occur in a multilane system wherein each lane includes a reaction chamber that can process samples at

the same time, and heating of each reaction chamber. Contrary to Mr. Israelson's false representations to the Examiner, Wilding thus discloses a multi-lane microfluidic cartridge, each lane comprising a PCR reaction zone with heating for each reaction zone.

60. Mr. Israelson's intentionally false representations while he was acting on behalf of and under the direction of BD regarding Wilding during the '900 prosecution were material and made with the intent to deceive the USPTO, and in fact did deceive the Examiner into allowing the amended claims over Wilding.

61. Absent Mr. Israelson's false and misleading material representations to the USPTO, the Examiner would not have issued the claims of the '900 patent because Wilding, in combination with other references cited by the Examiner, discloses the claimed invention, including the claim elements misrepresented by Mr. Israelson as missing from Wilding's disclosure.

62. Mr. Israelson's continued pattern of misconduct, including Mr. Israelsen's false and misleading statements of fact in prosecuting the '900 patent, while acting on behalf of and under the direction of BD, violated Mr. Israelsen's and BD's duty of candor and good faith and fair dealing required by USPTO's Rule 56. The '900 patent is thus enforceable due to inequitable conduct.

COUNT IV – BREACH OF CONTRACT

63. NeuMoDx incorporates by reference paragraphs 1-62 of its counterclaims and its affirmative defenses above as though fully set forth herein.

64. In late 2011, Williams and Brahmasandra contacted senior executives at BD and shared Williams' intentions to actively pursue, with the support of venture capital, a startup nucleic acid testing systems company.

65. Brahmasandra informed BD that he was interested in joining MSC, but that he was prevented from doing so because of the non-compete agreement with BD.

66. Brahmasandra requested a waiver of his non-compete agreement to work with Williams at MSC to develop a nucleic acid-based system for performing rapid identification.

67. On February 23, 2012, BD and Brahmasandra entered into an "Amendment to Employment Agreement." BD agreed that "Employee (Brahmasandra) shall be permitted to engage in any activity relating to nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification contemplated by Molecular Systems Corporation."

68. BD also agreed that the "Proposed Business (MSC) shall not be deemed to Compete with or be Competitive with the Company (HandyLab) or any of its Affiliates for the purpose of this Agreement."

69. MSC is an intended third party beneficiary of the February 23, 2012 Agreement.

70. There was consideration for the Amended Agreement. Brahmasandra was required to "use "commercially reasonable efforts" to schedule a meeting with "representatives of BD's exploratory technology group for the purpose of providing additional information about the Proposed Business, subject to the execution and delivery of a customary non-disclosure agreement…".

71. Brahmasandra complied with his obligations. On several occasions during 2012 and 2013, MSC, which changed its name in 2012 to NeuMoDx, shared its business purposes, system architecture, technology, patents/patent applications and financing/financing plans with BD.

72. In July 2013, NeuMoDx inquired with a senior BD executive about BD's interest in participating in a venture financing round of NeuMoDx. NeuMoDx provided a two-page

summary of its system and technology and informed BD that NeuMoDX "had developed technology combining the best attributes of both integrated cartridge and microplate-based, liquid handling system, with the resulting platform to offer improved ease of use, lower costs, and higher performance compared to other nucleic acid testing systems."

73. After 2013, NeuMoDx met with representatives of BD at least annually at industry trade shows at which NeuMoDx provided BD with demonstrations of the NeuMoDx products and answered questions about the technology. During the parties' meetings, NeuMoDx shared its technology, including confidential aspects of its technology, with BD.

74. BD has now breached the Amended Agreement with Brahmasandra and MSC/NeuMoDx, the intended third party beneficiary of the Agreement, by suing NeuMoDx for the very nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification activity that BD agreed Brahmasandra and MSC/NeuMoDx could engage in.

75. NeuMoDx has been harmed and suffered damages as a direct and proximate result of BD's breach of contract, including but limited to the time, resources, attorney's fees, costs and expenses incurred in defending the present lawsuit filed by BD against NeuMoDx, as well as actual damages, reputational damages and lost opportunities resulting from BD's breach.

RESERVATIONS OF RIGHTS

The above affirmative defenses and counterclaims are based upon incomplete information because (i) NeuMoDx has not yet been afforded any significant discovery in this case; and (ii) NeuMoDx's discovery and investigation of the claims, counterclaims and defenses in this action are continuing. Therefore, NeuMoDx reserves the right to supplement and/or amend such defenses and/or counterclaims if and when further information becomes available.

PRAYER FOR RELIEF

WHEREFORE, NeuMoDx prays for entry of a judgment:

1. Dismissing the Complaint with prejudice;

2. Declaring that NeuMoDx is not infringing, and has not infringed, directly, contributorily, or by inducement, any claim of the '308, '069, '708, '900, '103, and '787 patents, either literally or under the doctrine of equivalents;

3. Declaring that the claims of the '308, '069, '708, '900, '103, and '787 patents are invalid and/or unenforceable under 35 U.S.C. §§ 102, 103, and /or 112;

4. Declaring the '708 patent, the '900 patent, and their downstream family members to be unenforceable due to inequitable conduct;

5. Declaring that this case is "exceptional" under 35 U.S.C. § 285 and awarding NeuMoDx its reasonable attorney's fees and costs;

6. Enjoining BD from enforcing the '308, '069, '708, '900, '103, and '787 patents against NeuMoDx or any of NeuMoDx's current or future customers;

7. Declaring that BD has breached the February 23, 2012, BD "Amendment to Employment Agreement" by filing the present lawsuit;

8. Awarding NeuMoDx damages for BD's breach of February 23, 2012, BD "Amendment to Employment Agreement", including but not limited to the time, resources, attorney's fees, costs and expenses incurred in defending the present lawsuit filed by BD against NeuMoDx, as well as actual damages, reputational damages, lost opportunities resulting from BD's breach, and pre and post-judgment interest.

9. Awarding to NeuMoDx any further necessary and proper relief under 28 U.S.C. § 2202;

10. Directing BD to pay all costs and expenses incurred by NeuMoDx in this action, including reasonable attorneys' fees; and

11. Such other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, NeuMoDx hereby demand a trial by jury on all issues so triable.

Dated: October 4, 2019

Respectfully submitted,

FARNAN LLP

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